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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,512	05/01/2001	Rachel Meyers	MP100-185P1R2M	5523

7590 04/01/2005
INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS INC
40 LANDSDOWNE STREET
CAMBRIDGE, MA 02139

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,512

Applicant(s)

MEYERS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 94 and 96-104 is/are allowed.
- 6) ☒ Claim(s) 83-93 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07/29/02.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A (Sequence Alignment)

2c

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/2005 has been entered. Since all the previously rejected claims are cancelled, the rejection set forth in the prior Office action is moot.

Claim 83-104 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found.

Claim Rejections - 35 USC § 112

Claims 83-93, and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is made because of the new limitation "a polypeptide which is at least 95 % identical" to SEQ ID NO:2 or "a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:1 or 3", wherein the claimed polypeptide has

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protease activity in base claim 83. The specification as originally filed does not reasonably communicate that the claimed invention is a method using a polypeptide which is at least 95 % identical to SEQ ID NO:2 or a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:1 or 3, wherein the claimed polypeptide has protease activity. This new matter rejection is also made for claim 95, drawn to "a membrane-bound form of an isolated polypeptide".

Applicant states that support for the new claims are found in the previously presented claims, and pages 49-92 of the specification. However, the Office could not find support in the specification originally filed. Applicant is kindly requested to point out the support for the rejected limitation in the specification as originally filed since the support is not apparent to the Office.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 83-87, 89-91, and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. 6,294,663 (the '663 patent, issue, filed 02 March 2000).

Claims 83-87, 89-91, and 93 have two part active steps, i.e. contacting SEQ ID NO: 2 protein with a compound (as listed in claims 87, and 89) and determine whether

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the compound interacts with the protein, wherein the interaction is determined by the various art-known method listed in claim 93.

The '663 patent discloses a protein sequence (i.e. SEQ ID NO: 2) that is at least 95 % identical to instant SEQ ID NO: 2 (note Exhibit A, the attached sequence alignment). The instant claims read on the immunohistochemistry assay of the prior art at Fig. 7.

Allowable Subject Matter

Claims 94, and 96-104 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Judy Ladrangan for Art Unit 1642 whose telephone number is 571-272-0536.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

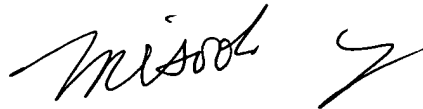
A handwritten signature in black ink, appearing to read "Misook Yu", with a stylized flourish at the end.

EXhibit A

GenCore version 5.1.6
Copyright (c) 1993 - 2004 CompuGen Ltd.

OM protein - protein search, using sw model

Run on: May 5, 2004, 15:45:40 ; Search time 22 Seconds
(without alignments)
1063.026 Million cell updates/sec

Title: US-09-846-512-2

Perfect score: 2443
Sequence: 1 MGENDPVAVAPSPRSLSFG.....TRVTSFLDMTHQWERDLKT 453

Scoring table: BLOSUM62

Gapop 10.0, Gapext 0.5

Searched: 389414 seqs, 51625971 residues

Total number of hits satisfying chosen parameters: 389414

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Listing first 45 summaries

Database: Issued Patents AA:
1: /cgn2_6/ptodata/2/1aa/5a_COMB.pep:*
2: /cgn2_6/ptodata/2/1aa/5b_COMB.pep:*
3: /cgn2_6/ptodata/2/1aa/6a_COMB.pep:*
4: /cgn2_6/ptodata/2/1aa/6b_COMB.pep:*
5: /cgn2_6/ptodata/2/1aa/6c_COMB.pep:*
6: /cgn2_6/ptodata/2/1aa/6d_COMB.pep:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query	Match Length	ID	Description
1	2385.5	97.6	454	US-09-518-046-2	Sequence 2, Appl1
2	2206	95.3	455	US-09-261-416-2	Sequence 2, Appl1
3	1354	55.4	294	US-09-518-046-4	Sequence 4, Appl1
4	885	36.2	492	US-09-342-749-2	Sequence 2, Appl1
5	885	36.2	492	US-09-681-840-2	Sequence 2, Appl1
6	874	35.8	492	US-09-685-165A-895	Sequence 23, Appl1
7	862	35.3	157	US-09-518-046-23	Sequence 23, Appl1
8	696	28.3	283	US-08-807-151-1	Sequence 1, Appl1
9	696	28.3	283	US-09-478-957-1	Sequence 4, Appl1
10	674	27.6	417	US-09-820-002-4	Sequence 2, Appl1
11	669.5	27.4	798	US-08-200-900A-2	Sequence 2, Appl1
12	669.5	27.4	798	PCT-US94-00616-2	Sequence 2, Appl1
13	665	27.2	423	US-09-656-002-2	Sequence 2, Appl1
14	665	27.2	423	US-09-000-846-2	Sequence 2, Appl1
15	658	26.9	435	US-09-851-588-8	Sequence 6, Appl1
16	658	26.9	435	US-09-851-588-8	Sequence 6, Appl1
17	656.5	26.9	376	US-09-820-002-2	Sequence 2, Appl1
18	656.5	26.9	406	US-09-851-588-6	Sequence 3, Appl1
19	585.5	25.0	256	US-09-027-137-3	Sequence 3, Appl1
20	585.5	25.0	256	US-09-644-600A-3	Sequence 3, Appl1
21	585.5	25.0	256	US-08-654-600A-3	Sequence 3, Appl1
22	580.5	23.8	255	US-08-944-483-67	Sequence 6, Appl1
23	579.5	23.7	638	US-08-681-151-3	Sequence 25, Appl1
24	571	23.4	418	US-08-508-448C-25	Sequence 82, Appl1
25	571	23.4	418	US-09-370-838-83	Sequence 83, Appl1
26	571	23.4	418	US-09-370-838-83	Sequence 62, Appl1
27	569	23.3	418	US-09-370-838-62	Sequence 62, Appl1

28	543.5	22.2	855	US-09-027-137-2	Sequence 2, Appl1
29	543.5	22.2	855	US-09-644-600A-2	Sequence 2, Appl1
30	543.5	22.2	855	US-09-654-600A-2	Sequence 2, Appl1
31	539.5	22.1	232	US-08-508-448C-19	Sequence 13, Appl1
32	539	22.1	248	US-08-944-483-63	Sequence 63, Appl1
33	536.5	22.0	235	US-08-807-151-3	Sequence 3, Appl1
34	536.5	22.0	235	US-08-807-151-3	Sequence 3, Appl1
35	532.5	21.8	285	US-09-023-942A-26	Sequence 26, Appl1
36	526	21.5	338	US-08-991-761A-10	Sequence 10, Appl1
37	525.5	21.5	235	US-08-944-483-65	Sequence 65, Appl1
38	523.5	21.4	790	US-08-991-761A-13	Sequence 13, Appl1
39	523	21.4	98	US-09-518-046-17	Sequence 17, Appl1
40	522.5	21.4	407	US-09-734-675-4	Sequence 4, Appl1
41	519	21.2	405	US-09-734-675-4	Sequence 2, Appl1
42	507	20.8	314	US-09-008-271A-3	Sequence 257, App
43	507	20.8	314	US-09-907-784A-257	Sequence 257, App
44	507	20.8	314	US-09-905-125A-257	Sequence 257, App
45	507	20.8	314	US-09-902-775A-257	Sequence 257, App

ALIGNMENTS

RESULT 1				
Sequence 2, Application US/09518046				
Percent No. 6294663				
GENERAL INFORMATION:				
APPLICANT: Underwood, Timothy J.				
TITLE OF INVENTION: Transmembrane Serine Protease Overexpressed				
FILE REFERENCE: 061993CIP				
CURRENT FILING DATE: 2000-03-02				
EARLIER APPLICATION NUMBER: 09/261,416				
NUMBER OF SEQ ID NOS: 153				
SEQ ID NO. 2				
LENGTH: 454				
TYPE: PRT				
ORGANISM: Homo sapiens				
FEATURES:				
OTHER INFORMATION: complete amino acid sequence of TADG-12				
US-09-518-046-2				
QY	Query Match	97.6%	Score 2385.5; DB 3; Length 454;	
QY	Best Local Similarity	97.8%; Pred. No. 1.3e-223;		
QY	Matches	444; Conservative	2; Mismatches	7; Indels 1; Gaps 1;
DB	1 MGENDPVAVAPSPRSLSFGDLDTKISPVAPDAVAAGQISLPLKRF-PIVIGIAL	59		
QY	1 MGENDPVAVAPSPRSLSFGDLDTKISPVAPDAVAAGQISLPLKRF-PIVIGIAL	60		
DB	60 ILAALIGLTHPCGSGKTRCRSSPKCITELIARCGVSPCKGGEVRCVRVGNMAYLV	119		
QY	60 ILAALIGLTHPCGSGKTRCRSSPKCITELIARCGVSPCKGGEVRCVRVGNMAYLV	120		
DB	61 ILAALIGLTHPCGSGKTRCRSSPKCITELIARCGVSPCKGGEVRCVRVGNMAYLV	120		
QY	120 FTASMTKMSDDMKGHVAVACAQZGPPSYSSDMLRVSSLECOFEEFVSIIDHLLPDD	179		
DB	121 FTASMTKMSDDMKGHVAVACAQZGPPSYSSDMLRVSSLECOFEEFVSIIDHLLPDD	180		
QY	180 KVTALHSHVYVRGSGAGSVVITLQCAAGHRGVSRRVAGNMELLSQPMOASLQFOGY	239		
DB	181 KVTALHSHVYVRGSGAGSVVITLQCAAGHRGVSRRVAGNMELLSQPMOASLQFOGY	240		
QY	240 HLCGGSVITLMTITTAACVVDLYLPKSTIOVGLVLLNDPASHVYKIVYHAKKPK	299		
DB	241 HLCGGSVITLMTITTAACVVDLYLPKSTIOVGLVLLNDPASHVYKIVYHAKKPK	300		
QY	300 RLGDIALMKGAPLTFTENIOPVCLPNSSENFPGKTCMTSGCAITBOGDASPTVANA	359		

Filed March 2, 2000

